In the United States Court of Federal Claims

No. 14-699V

(E-Filed: January 24, 2020)[1]

JAMILEH BERENJI and BAHMAN YOUSEFI, on behalf of S.Y., Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Vaccinations (Influeza, Measles-Mumps-Rubella (MMR), Varicella, Pneumococcal Conjugate (Prevnar)); National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012); Deferential Review of Special Master's Fact Finding and Weighing of Evidence.

Mark T. Sadaka, Englewood, NJ, for petitioner.

Kyle E. Pozza, Trial Attorney, with whom were Joseph H. Hunt, Assistant Attorney General, C. Salvatore D'Alessio, Acting Director, Catharine E. Reeves, Deputy Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

CAMPBELL-SMITH, Judge.

On August 30, 2019, the special master denied compensation to petitioners under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (the Vaccine Act). See ECF No. 111.[2] On September 27, 2019, petitioners filed a

[1] Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims (Appendix B to the Rules of the United States Court of Federal Claims), this opinion was initially filed under seal on January 6, 2020. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before January 21, 2020. No proposed redactions were submitted to the court.

[2] The court notes that proceedings before the special master in this case were unusually complex. For clarity, the court emphasizes that its review in this opinion is limited to the special master's August 30, 2019 decision denying compensation to petitioners, ECF No. 111.

motion for review of the special master's August 30, 2019 decision and a memorandum in support of their motion for review.[3] See ECF No. 114, ECF No. 115. Respondent filed its response brief on October 23, 2019. See ECF No. 119. Petitioners' motion is fully briefed and ripe for decision. As explained below, the special master's entitlement decision survives this court's review. Accordingly, the court must **DENY** petitioners' motion for review.

I. Background

On August 4, 2014, petitioners filed this case seeking compensation for an injury allegedly suffered by their minor child as the result of receiving influenza (flu), measles-mumps-rubella (MMR), varicella, and pneumococcal conjugate (Prevnar) vaccinations, on October 17, 2011. See ECF No. 1. In reaching his decision, the special master reviewed the child's medical history in great detail, including the following facts relevant to the court's analysis of petitioners' motion for review.[4]

Petitioners' son was born in October 2010. See ECF No. 111 at 6. He developed normally and was generally healthy prior to his well-child examination on October 17, 2011. See id. at 7. At that appointment, the child received "his first MMR vaccination and first influenza vaccination . . . as well as his first varicella vaccination and his fourth pneumococcal vaccination." Id. The child's mother reported to the pediatrician that she had a history of anemia. Accordingly, the doctor recommended that the child undergo a hemogram (complete blood count). See id. The child's blood was drawn the same afternoon, and results showed that his platelet count was "significantly low," his hemoglobin count and hematocrit levels were "low," and that his white blood cell count was "normal." Id. Repeated testing showed a decrease in all levels, most dramatically in the platelet count. See id.

In light of these test results, the pediatrician referred the child to a specialist at the Lucile Packard Children's Hospital at Stanford University. See id. at 7-8. Following additional testing, on October 19, 2011, the specialist diagnosed the child with Evans syndrome, "'an autoimmune process that results in hemolytic anemia and

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[3] Although petitioners' memorandum is properly titled on the document, petitioners' counsel selected the motion event when filing petitioners' memorandum in the court's case management/electronic case filing (CM/ECF) system. For proper case management purposes and docket clarity, the court must rule separately on petitioners' memorandum and motion for review in the final ordering language of this opinion.

[4] For clarity of the narrative, the court cites to the special master's decision and omits direct citations to the record therein. The court also notes that the special master's decision includes a more detailed description of the child's medical history than is necessary for the analysis in this opinion.

thrombocytopenia.'" Id. at 8. On October 23, 2011, the child was "presented for emergency attention following a one-day history of vomiting and diarrhea, as well as a fever which had risen to approximately 104 degrees Fahrenheit." Id. The child received antibiotics, but two days later, he still had a fever of 102 degrees Fahrenheit. See id. On October 25, 2011, the child's pediatrician administered a second dose of antibiotics, and discussed the cause of the child's condition with petitioners. The doctor noted:

> "Parents understandably very devastated by his recent diagnosis and mom still very concerned that his recent 12-month vaccines, most notably, the MMR, was the etiology of his current condition. Discussed that while the stress of the vaccines may have triggered the disease to surface, it certainly was not the cause of his Evan[s] syndrome."

Id. (special master's decision quoting doctor's note).

On October 28, 2011, the child's hematologist-oncologist noted that his fever had resolved, but also recorded that the child had developed a rash. See id. at 9. The doctor believed the rash was "'probably post-viral,'" and advised the child's mother that if the child had developed measles after receiving the MMR vaccination "'this rare occurrence, concurrent with an apparently autoimmune pancytopenia, may raise a question of previously undiagnosed immune deficiency.'" Id. Following additional testing, the doctor recommended that the child be admitted to the hospital for observation. See id. On his way to the hospital, the child experienced a seizure. See id. While at the hospital, the child underwent still more testing which showed further decreases in his platelets, hemoglobin, and hematocrit levels, but a slight increase in his white blood cell count, though it remained lower than normal. See id. On October 29, 2011, the child received additional antibiotics and intravenous immunoglobulin (IVIg). See id.

The child's pediatric infectious disease specialist recorded, on October 29, 2011, that the child's "'vaccinations could not have caused his anemia and thrombocytopenia, which were documented less than one hour afterwards.'" Id. She also noted that "'it is possible that [the child's] fever and rash (and less likely, afebrile seizure) were caused by MMR, and that these are unrelated to the cause of his underlying bone marrow suppression/autoimmune hemolytic anemia.'" Id.

On October 31, 2011, the child was evaluated by an immunologist who noted that "'[i]t is possible that he had two distinct processes happening simultaneously.' First, Evans syndrome probably represented a 'true autoimmune process.' Second, the MMRV vaccine may have caused a self-limited febrile seizure episode." Id. (citations omitted). The child was discharged from the hospital, with a steroid prescription, on November 2, 2011. See id.

On November 4, 2011, the child was seen by a pediatrician as a follow-up to his hospitalization. She found that the child was "doing well without further rash, fever, or seizure activity." Id. at 10. She further noted:

> "[A]fter extensive workup by Infectious Disease and Immunology, the general thought is that [the child] developed some rare but known complication from his measles, mumps, and rubella vaccine which included fever, a rash and seizure . . . . It is therefore likely that [the child] had two different processes that occurred at the same time. We also believe that [the child's] Evans syndrome did not stem from this measles, mumps, and rubella, as his thrombocytopenia was noted just one hour after his vaccine."

Id. (special master's decision quoting doctor's note). And on November 10, 2011, the hematologist-oncologist noted that the child's "'apparent vaccine-related illness has since resolved.'" Id.

In December 2011, the child's doctors "tried to taper him off steroids," but he was admitted to the hospital again on December 27, 2011, after tests showed low hemoglobin and platelets. See id. "On December 31, 2011 [the child] started a five-day course of IVIg which was associated with improved blood counts," and "[h]e was discharged with steroids on January 5, 2012." Id.

"Due to continued thrombocytopenia on oral steroids, [the child] received four infusions of Rituximab (an immunosuppressant) between February 13 and March 15, 2012. However, due to a lack of sustained response, on April 17, 2012, he was started on cyclosporine (another immunosuppressant)." Id. In what doctors concluded was likely an adverse reaction to the cyclosporine, the child experienced "an episode of non-responsiveness and shaking lasting approximately 15 minutes," on June 1, 2012. The child experienced another seizure later the same month, and "[c]yclosporine was discontinued and he was started on Keppra (an anti-seizure medication)." Id.

On July 17, 2012, the child "was started on CellCept (another immunosuppressant)." Id. He was admitted to the hospital again from September 8-11, 2012, due to rectal bleeding. See id. While hospitalized "he received a platelet transfusion and IVIg." Id.

Test results on February 12, 2013, indicated that his "T and B cell subsets . . . were normal," meaning that "he had recovered from the Rituximab therapy in February-March 2012." Id. at 11. Also on February 12, 2013, CellCept was discontinued. Id. "Afterwards, [the child] was increasingly fatigued and less interested in playing and ambulating. A non-productive cough present since November 2012 seemed to worsen in frequency and productivity." Id.

On February 22, 2013, the child underwent a bone marrow biopsy, and was admitted to the hospital and began using supplemental oxygen due to his difficulty breathing. See id. Because the results of the initial biopsy were "suspicious for malignancy," a repeat biopsy was performed on March 1, 2013, and showed:

> While platelets are markedly decreased with circulating giant forms, the bone marrow aspirates and biopsy sections show an abundant megakaryocytic hyperplasia, including small immature forms. The finding of hyperplastic megakaryocytes suggests the etiology of the thrombocytopenia is not poor platelet production, but rather peripheral destruction and/or sequestration. Both red cell and megakaryocyte/platelet findings are consistent with immune-mediated destruction of red cells and platelets and have been described in Evans syndrome.

Id.

The child was transferred to pediatric intensive care on March 7, 2013, "after he developed seizure-like activities with tonic-clonic movements and ineffective breathing. He was stabilized with non-invasive respiratory support." Id. After experiencing another seizure on March 9, 2013, he was started on Keppra, and the seizure activity subsided for the remainder of his hospitalization. On March 28, 2013, a lung biopsy confirmed that the child had pulmonary veno-occlusive disease (PVOD) "which related back to and explained the respiratory problems which had begun in mid-February 2013." Id. He was "discharged with supplemental oxygen on April 8, 2013." Id.

In August 2013, the child was admitted to the hospital "due to a pulmonary infection that exacerbated his PVOD." Id. The child was hospitalized again on September 26, 2013, "for worsening jaundice, difficulty breathing, and high levels of bilirubin and transaminases (liver enzymes)." Id. at 12. The child tested positive for rhinovirus and parainfluenza, and a "liver cell biopsy showed syncytial giant cell hepatitis, suggestive of autoimmune hepatitis." Id. He was discharged on December 26, 2013. See id.[5]

On August 4, 2014, petitioners filed their claim alleging that their son suffered injuries as a result of receiving the flu, MMR, varicella, and Prevnar vaccinations. See ECF No. 1. The special master agreed with the parties from the outset that "expert reports would be necessary to understand the complex issues concerning [the child's] medical condition and the timing in this case." ECF No. 111 at 2. Petitioners filed three reports from Dr. M. Eric Gershwin, M.D., in support of vaccine causation. See id. at 2-3.

[5] After the child was diagnosed with hepatitis, he continued to struggle with hospitalizations and serious medical complications. No further recitation of the child's condition is necessary for purposes of this court's analysis, however, because petitioners' motion for review addresses a narrow aspect of the special master's decision.

Respondent filed two reports from Dr. Mehrdad Matloubian, M.D., and one report from Dr. Joan Cox Gill, M.D., in which they disagreed with Dr. Gershwin on the causation issue. See id. The special master held an entitlement hearing on August 14, 2017, at which he heard testimony from petitioner Jamileh Berenji, Dr. Gershwin, Dr. Matloubian, and Dr. Gill. See id. at 3.

After a lengthy consideration of the facts and argument, the special master's August 30, 2019 decision concluded as follows:

> [T]here can be little question that [the child's] condition became markedly worse after receiving the vaccines on October 17, 2011. His treating doctors generally thought that the process including fever, seizure and full body rash were likely attributable to the vaccine. However, that short-term injury, if attributed to the vaccines, did not last for more than six months. It is significantly more difficult to find a logical and temporal association between [the child's] vaccinations and his long-term course which is at least somewhat similar to other patients with Evans syndrome. The available literature on this very rare disease suggests that Evans syndrome is chronic and refractory to treatment. [The child's] development of anitnuclear antibodies, antiphospholipid antibodies, hepatitis, and PVOD seems particularly rare. However, those conditions are unlikely to be caused by B cells stimulated by the vaccines, which were eliminated and replaced in the intervening time period. Thus, there is not a logical sequence of cause and effect or an acceptable temporal association between the vaccinations and [the child's] long-term course.

Id. at 24-25 (footnote omitted). For these reasons, the special master ruled to dismiss petitioners' complaint. Id. On September 27, 2019, petitioners filed their motion for review.

II. Legal Standards

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. 42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]'" de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing Althen v. Sec'y Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)) (alteration in original).

This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master's judgment is under scrutiny.

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The third standard of review, abuse of discretion, is applicable when the special master excludes evidence or otherwise limits the record upon which he or she relies. See id. at 870. As this court has stated, the third standard applies to the special master's evidentiary rulings. Stillwell v. Sec'y of Health & Human Servs., 118 Fed. Cl. 47, 55 (2014) (citation omitted), aff'd, 607 F. App'x 997 (Fed. Cir. 2015). Determinations subject to review for abuse of discretion must be sustained unless "manifestly erroneous." Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 53 (2005) (citations omitted); see also Milmark Servs., Inc. v. United States, 731 F.2d 855, 860 (Fed. Cir. 1984) (holding that decisions within the trial court's discretion are to be sustained unless "manifestly erroneous") (citation omitted).

A petitioner may obtain compensation if he or she "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by" certain vaccines, including the HPV vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(ii). A case for significant aggravation of an off-Table claim requires proof, by a preponderance of the evidence, of:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1360 (Fed. Cir. 2013) (referring to the Loving test as "the correct law").

III. Analysis

In their motion for review, petitioners challenge a narrow aspect of the special master's decision. Petitioners argue that the special master improperly "stops short of finding that lung (veno-occlusive disease) and liver (autoimmune hepatitis) injuries that [the child] suffered could have been caused by the vaccines largely based on one undisclosed unsupported opinion made by respondent's expert Dr. Matloubian on the activity of [the] medication Rituximab in this specific case." ECF No. 114 at 5. Petitioners divide this objection into two parts. First, they claim that "[r]eliance on an undisclosed net opinion impermissibly heightened petitioner's burden in proving causation."[6] Id. at 6. And second, petitioners contend that "[a]ccepting unsupported testimony at [the] hearing on key scientific issues was arbitrary, capricious, and an abuse of the Special Master's discretion." Id. at 7. The court will address each argument in turn.

A. The Special Master Applied the Correct Standard in Evaluating Petitioner's Causation Evidence

Petitioners argue that their "burden in prov[ing] causation was impermissibly heightened by requiring a higher scientific standard beyond what is required under Althen and its progeny." Id. at 6. Specifically, they claim that "[p]etitioner's burden was heightened by crediting Dr. Matloubian's net opinion that 99% of [the child's] B cells were destroyed by treatment with Rituximab." Id. at 6-7 (citing ECF No. 111 at 24). Petitioners' argument on this point consists of the following:

> First, Dr. Matloubian's opinion regarding Rituximab was never disclosed and should be stricken from the record. Second, he provided zero supporting evidence for his testimony about the action of Rituximab in this specific case making his opinion a net opinion and unreliable. . . . Not only does Dr. Matloubian fail to provide any support generally about the activity of Rituximab on B cells in a pediatric patient, he also fails to point to any support for his opinion in the medical record again making it an inadmissible net opinion. In fact, the current FDA approved prescription drug label for Rituximab provides the following:
>
> 8.4 Pediatric Use

[6] Petitioners repeatedly use the term "net opinion" to refer to Dr. Matloubian's opinion at issue, but they fail to define it. See, e.g., ECF No. 114 at 6-7. To the court's knowledge, "net opinion" is not a term of art, nor is it a term in common usage such that familiarity with the term may be presumed. For this reason, the court does not include any specific discussion of what petitioners mean to argue on this point.

> The safety and effectiveness of RITUXAN in pediatric patients have not been established.
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> Source: https://www.gene.com/download/pdf/rituxan_prescribing.pdf
>
> Given the fact that it was not clear how instrumental Dr. Matloubian's undisclosed opinion was to the Special Master's decision in this case until he issued his decision, petitioner should be given the opportunity to address the undisclosed opinion.

Id. at 7 (citations and footnotes omitted).

This argument does not articulate how the special master's treatment of Dr. Matloubian's opinion affected petitioner's burden of proof. It does suggest, however, that: (1) respondent failed to meet a disclosure obligation; (2) the special master improperly failed to require documentation in support of Dr. Matloubian's oral testimony; and (3) that the special master was required to notify the parties of the evidence he found persuasive prior to issuing his decision. None of these requirements are reflected in the rules or practices of the vaccine program.

The special master repeatedly affirmed the correct burden of proof, stating that petitioners were required to prove their case by a preponderance of the evidence. See, e.g., ECF No. 111 at 4, 15, 18 (citing Loving, 86 Fed. Cl. at 144). Indeed, the special master was expressly cognizant of avoiding the very issue nominally raised by petitioners. He wrote that "special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury." Id. at 15 (citing Contreras v. Sec'y of Health & Human Servs., 121 Fed. Cl. 230, 245 (2015), vacated on other grounds, 844 F.3d 1363 (Fed. Cir. 2017)). He also noted, however, that "this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence." Id. (citing W.C., 704 F.3d at 1356).

In addition, the special master diligently reviewed the evidence and arguments presented by the parties, and emphasized that he had considered the entire record in reaching his ultimate decision. See ECF No. 111 at 15-24 (discussing the various expert theories at length); id. at 2 n.3 ("Pursuant to Section 13(a)(1), in order to reach my decision, I have considered the entire record, including all of the medical records, expert testimony, and literature submitted by the parties."). And in reaching that decision, the special master was "entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to [him] and . . . as to the credibility of the persons presenting that evidence," including experts. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1326 (Fed. Cir. 2010)). As the special master stated, "[w]here both sides offer expert testimony, a special master's decision may be 'based on the credibility of the experts and the relative persuasiveness of their competing theories.'"

See ECF No. 111 at 6 (quoting Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010)). See also Vaccine Rule 8(b)(1), Rules of the United States Court of Federal Claims, Appendix B (" In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.").

The court concludes that the special master's consideration of Dr. Matloubian's testimony was not only proper, but because he found the testimony relevant and reliable, such consideration was required.

B. The Special Master's Consideration of Dr. Matloubian's Testimony Was Not Arbitrary, Capricious, or an Abuse of Discretion

Petitioner's second argument is one sentence long: "As articulated above, the Special Master's decision to rely on Dr. Matloubian's undisclosed unsupported decision on the issue of logical sequence of cause and effect was arbitrary and capricious." ECF No. 114 at 8. The court disagrees. For the reasons explained above, the special master's decision was well-founded and appropriately rendered.

IV. Conclusion

In the conclusion of his decision, the special master stated: "I wish to extend my sympathy to [the child] and his family in the light of the enormous suffering they have experienced in association with his Evans syndrome." ECF No. 111 at 25. The court likewise acknowledges the child's and the family's suffering and echoes the special master's sympathy. For the above-stated reasons, however, the court sustains the entitlement decision of the special master.

Accordingly, it is hereby **ORDERED** that:

(1) Petitioners' motion for review, filed as ECF No. 114 (memorandum) and ECF No. 115 (motion), is **DENIED**;

(2) The August 30, 2019 decision of the special master, ECF No. 111, is **SUSTAINED**;

(3) The clerk's office is directed to **ENTER** final judgment in accordance with the special master's August 30, 2019 decision, ECF No. 111; and

(4) The parties shall separately **FILE** any proposed redactions to this opinion, with the text to be redacted clearly blacked out, on or before **January 21, 2020**.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge